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Indian Standard

ELECTROTECHNICAL VOCABULARY

PART XXXXIII ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

(First Reprint APRIL 1990)

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Indian Standard

ELECTROTECHNICAL VOCABULARY

PART XXXXIII ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

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Indian Standard

ELECTROTECHNICAL VOCABULARY

PART XXXXIII ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

0. FOREWORD

0.1 This Indian Standard (Part XXXXIII) was adopted by the Indian Standards Institution on 18 February 1977, after the draft finalized by the Electrotechnical Standards Sectional Committee in consultation with the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 This standard covers definition of terms relating to electrical equipment used in medical practice.

0.3 In the preparation of this standard, considerable assistance has been derived from IEC Doc : 62A (Secretariat) 10 Draft — Recommendation for general safety requirements for electrical equipment used in medical practice.

0.4 This standard is one of the series of Indian Standards on electrotechnical vocabulary. ~~A list of Indian Standards so far published in this series is given on fourth cover page~~.

1. SCOPE

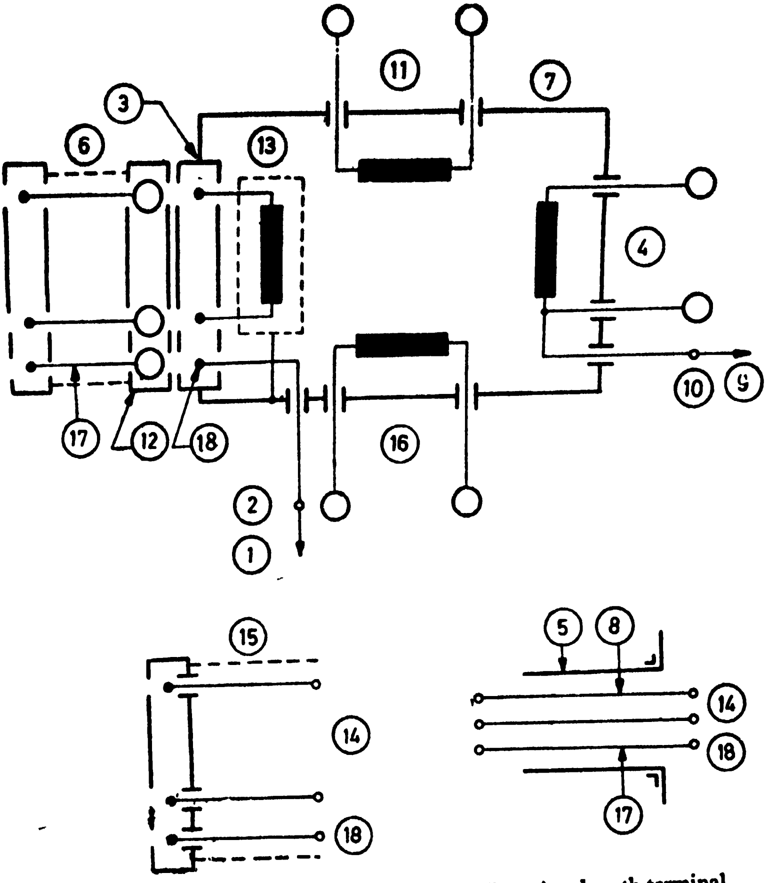
1.1 This standard (Part XXXXIII) covers definition of terms relating to electrical equipment used in medical practice.

2. TERMINOLOGY

2.1 Accessible Conductive Parts — Conductive parts which are separated from the mains part by insulation and which may be touched without the use of tools by operator or patient, for example, the enclosure of equipment or parts thereof.

2.2 Additional Protective Earth Terminal — A protective earth terminal provided in addition to the normal protective earth terminal for the purpose of providing protection against electric shock in case of single fault condition of the normal protective earth conductor (*see* Fig. 1).

2.3 Ambulance or Vehicle-Mounted Equipment — Equipment intended for installation in vehicles for road, rail, sea or air transport.



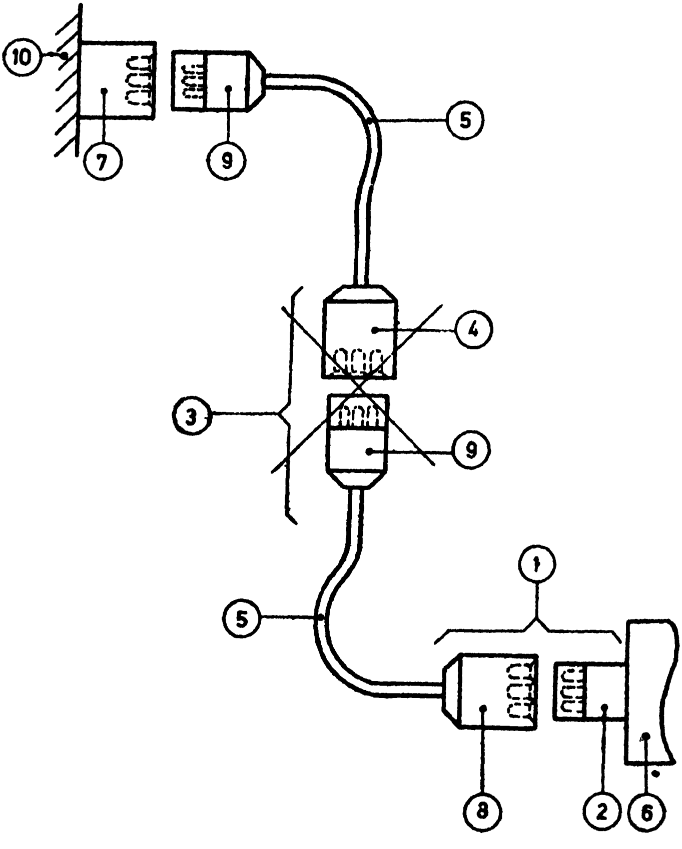
1 Additional protective earth conductor
2 Additional protective earth terminal
3 Appliance inlet (*see also* Fig. 2)
4 Applied part
5 Conduit
6 Detachable cord
7 Enclosure
8 Fixed wiring
9 Functional earth conductor
10 Functional earth terminal
11 Input part
12 Mains connector
13 Mains part
14 Mains terminal device
15 Non-detachable cord
16 Output part
17 Protective earth conductor
18 Protective earth terminal

Fig. 1 An Example of the Defined Terminals and Conductors

2.4 Anaesthetic-Proof (Equipment) — Under consideration.

2.5 Anaesthetic-Proof Equipment of Category G — Under consideration.

2.6 Appliance Coupler — A means enabling the connection at will, of a flexible cable or cord to equipment (*see* Fig. 2). It consists of two parts; an appliance connector and an appliance inlet.



1 Appliance coupler
2 Appliance inlet
3 Cable coupler
4 Connector
5 Detachable flexible cable or cord
6 Equipment
7 Fixed mains socket outlet
8 Appliance connector
9 Mains plug
10 Mains supply

FIG. 2 DETACHABLE MAINS CONNECTION

2.7 Appliance Inlet — That part of an appliance coupler incorporated in or fixed to the equipment, or intended to be fixed to it (*see* Fig. 1 and 2).

2.8 Appliance Connector — Part of an appliance coupler or of a cord set integral with or intended to be attached to the flexible cable or cord which is intended to be connected to the supply mains. An appliance connector is intended to be inserted into the appliance inlet of equipment (*see* Fig. 1 and 2).

2.9 Applied Part — The entirety of all parts which intentionally have a conductive connection with or come intentionally into contact with patients to be examined or treated.

NOTE 1 — For some equipment the individual specification on each type of electro-medical equipment may consider parts in contact with the operator as applied part (*see* Fig. 1).

NOTE 2 — An applied part may consist of:

a) a conductive surface, connected to protective earth, but not including the protective connection;

b) a non-conductive surface;

c) an electric circuit, parmanently connected to protective earth, but not including the protective connection;

d) an electric circuit or a conductive surface isolated from protective earth [isolated (floating) applied part]; and

e) an F-type isolated (floating) patient circuit or an F-type isolated conductive surface.

NOTE 3 — For an isolated (floating) applied part the conducting connection as seen from the patient into the equipment extends to the point(s) where the prescribed insulation and/or protective impedance is completed.

2.10 Basic Safety Insulation — The insulation necessary for basic protection against electric shock.

NOTE 1 — This insulation may also serve as operational insulation.

NOTE 2 — The basic safety insulation will normally need to be supplemented by an enclosure to prevent access to live parts to complete protection against electric shock. The basic safety insulation and the enclosure may be integral.

2.11 Body of the Equipment — All accessible conductive parts, accessible shafts of knobs, of handles, of grips and the like and for the purpose of tests, metal foil, not larger than 200 × 100 mm, applied in contact with all accessible surfaces of insulating material, not including non-accessible conductive parts.

2.12 Cathetar — A flexible tube for admitting or removing gases or liquids through channels of the body.

2.13 Class I Equipment — Equipment intended for connection to an external supply in which accessible conductive parts which may give rise to electric shock in the event of a fault occurring in the basic safety insulation of live parts connected to an external supply are provided with means to connect them to a protective earth conductor in the fixed wiring of the installation (*see* Fig. 3).

NOTE 1 — External supply includes supply from an external battery or an external convertor.

NOTE 2 — For equipment intended for use with a flexible cable or cord the 'means' includes a protective earth conductor as part of the flexible cable or cord and a mains plus with earthing contact.

NOTE 3 — The connection to the protective earth conductor is regarded as an additional protective measure against electric shock hazard.

NOTE 4 — For equipment intended for use with a detachable cord the 'means' includes an appliance inlet with earthing contact.

NOTE 5 — For equipment intended for permanent installation the 'means' includes a terminal for protective earthing.

NOTE 6 — Class I equipment may have parts with double insulation or reinforced insulation or parts operating at isolated extra-low voltage or at medical isolated extra-low voltage or accessible parts protected by protective impedance in cases where conductive parts of an electrical circuit have to be accessible to enable the equipment to function.

2.14 Class II Equipment — Equipment intended for connection to an external supply which will not give rise to electric shock in the event of a fault occurring in the basic safety insulation of live parts connected to an external supply because additional safety precautions which do not include provision for protective earthing or rely upon installation conditions are incorporated (*see* Fig. 4).

NOTE 1 — Examples of 'additional safety precautions' are supplementary insulation or the provision of reinforced insulation instead of basic safety insulation.

NOTE 2 — Protective impedance may be used as an 'additional safety precaution' in those cases where conductive parts of an electrical circuit have to be accessible to enable the equipment to function and the application of a Class I construction is precluded.

NOTE 3 — Class II equipment may be provided with means for connection with earth for functional (as distinct from protective) purposes.

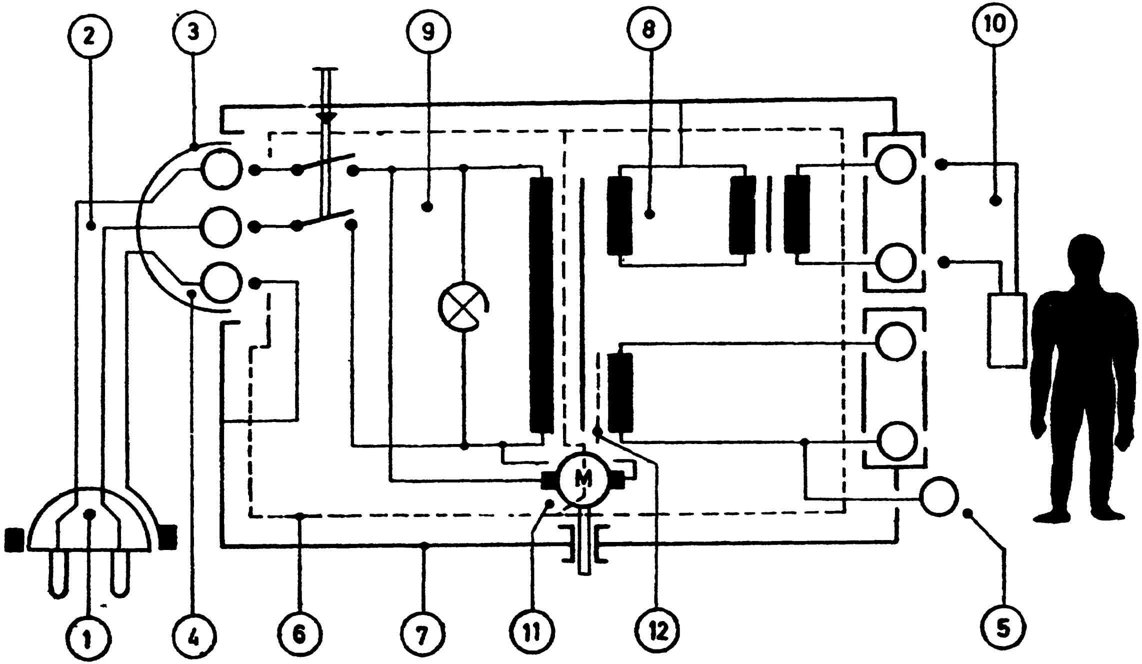
NOTE 4 — Class II equipment with an accessible conductive enclosure may be fitted with means for the connection of a potential equalization conductor to this enclosure.

NOTE 5 — Class II equipment may have parts operating at isolated extra-low voltage or at medical isolated extra-low voltage.

NOTE 6 — Class II equipment may have an enclosure made of insulating material or of accessible conductive material or of a combination of these.

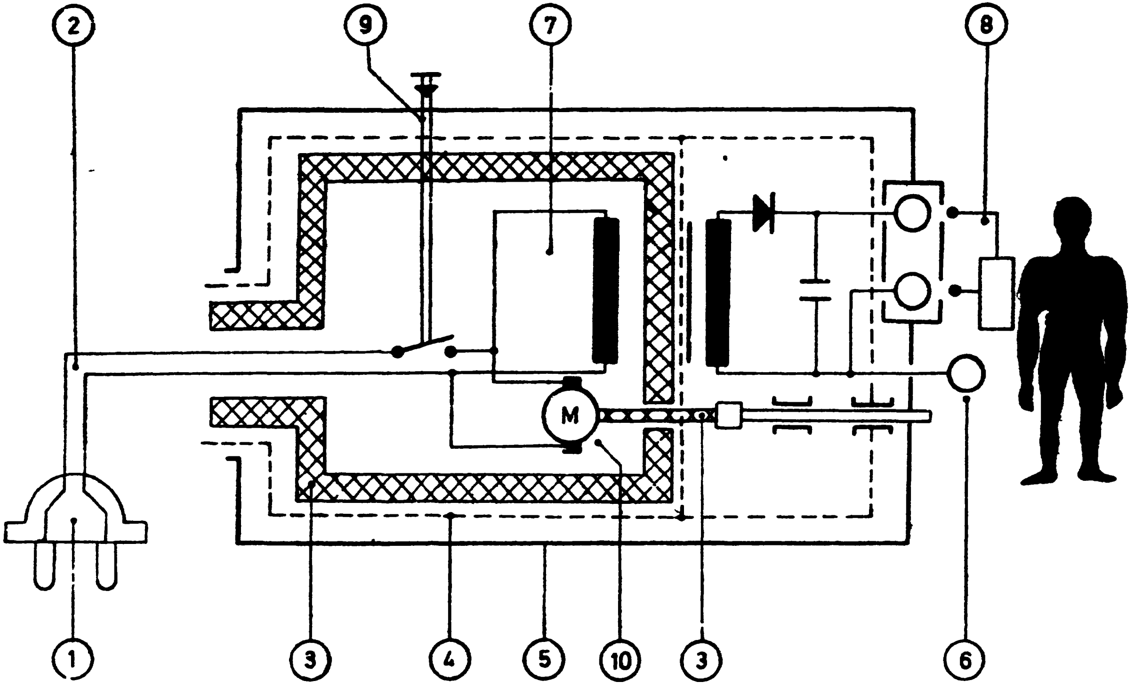
NOTE 7 — Class II equipment may be provided with means for maintaining the continuity of protective circuits. Such means shall be treated inside the equipment as if they were live parts.

2.15 Class III Equipment — Equipment intended for connection to an external supply which will not give rise to electric shock because it is designed for supply from isolated extra-low voltage only and in which no voltage higher than isolated extra-low voltage are generated (*see* Fig. 5).



1 Plug with protective earthing contact
2 Detachable, flexible supply cord
3 Appliance coupler
4 Protective earth contact and pin
5 Functional earth terminal
6 Basic safety insulation
7 Enclosure (accessible metal parts)
8 Intermediate circuit
9 Mains part
10 Applied part
11 Motor with accessible shaft
12 Supplementary insulation or protectively earthed screen

FIG. 3 AN EXAMPLE OF A PROTECTION CLASS I DESIGN



1 **Shaped plug**
2 Non-detachable, flexible supply cord
3 Basic safety insulation
4 Supplementary insulation
5 Enclosure (accessible conductive parts)
6 Functional earth terminal
7 Mains part
8 Applied part
9 Reinforced insulation
10 Motor with accessible shaft

FIG. 4 AN EXAMPLE OF A METAL-ENCLOSED PROTECTION CLASS II DESIGN

Note 1 — The combination of isolated supply and the restricted voltage are regarded as an additional protective measure against electric shock hazard.

Note 2 — If internal voltages higher than isolated extra-low voltage are generated additional safety techniques shall be applied.

Note 3 — Class III equipment is not normally earthed but the provision of earthing facilities does not exclude it from being regarded as Class III equipment.

Note 4 — For some intended applications the maximum voltage is restricted to medical isolated extra-low voltage.

2.16 Coefficient of Variation (C) — The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation :

$$C = \frac{S}{\overline{X}} = \frac{1}{\overline{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{n-i} \right]^{\frac{1}{2}}$$

where

S = estimated standard deviation of the population,
$\overline{X}$ = mean value of observations in sample,
X_i = i^{th} observation in sample, and
n = number of observations in sample.

2.17 Cold Condition — The condition obtained if the equipment is de-energized for a sufficiently long time to attain the ambient temperature.

2.18 Conductive Connection — A connection through which a current may flow exceeding the allowable leakage current.

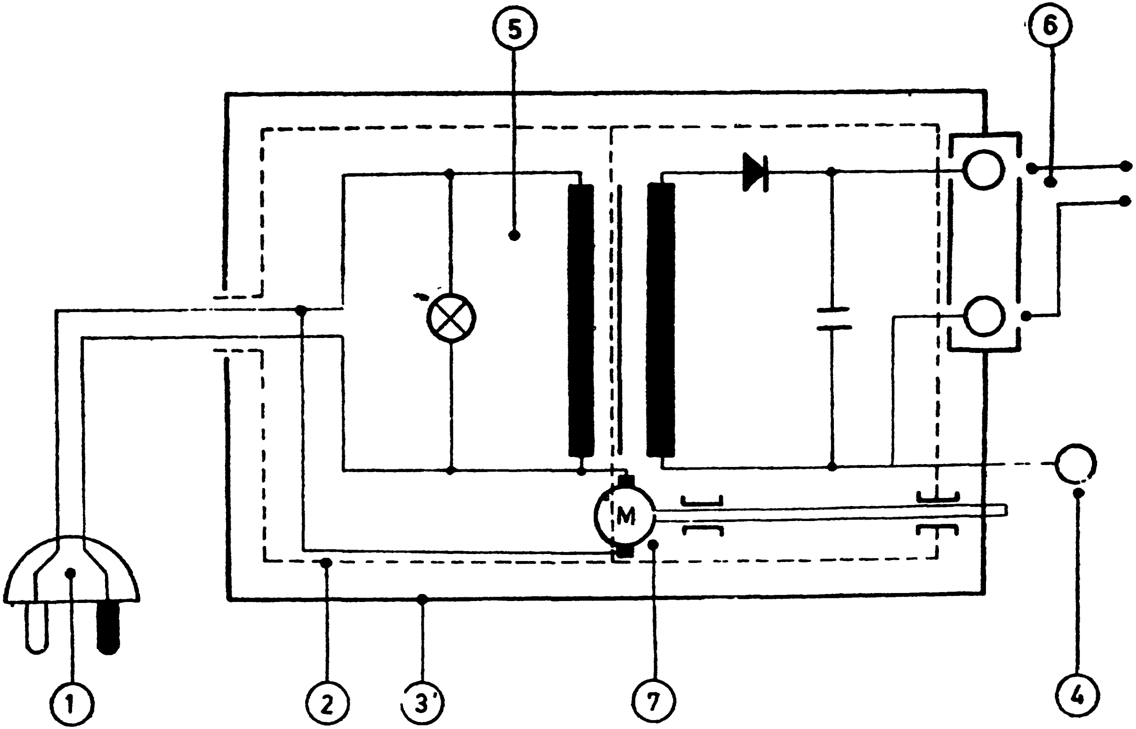
2.19 Continuous Operation — Operation under normal load for an unlimited period without the specified limits of temperature rise being exceeded.

2.20 Continuous Operation with Intermittent Loading — Operation in which the equipment is connected continuously to the mains. The stated permissible loading time is so short, that the long term on-load operating temperature is not attained. The ensuing interval in loading is, however, not sufficiently long to attain cooling down to the long term no-load operating temperature.

2.21 Continuous Operation with Short-time Loading — Operation in which the equipment is connected continuously to the mains. The stated permissible loading time is so short, that the long term on-load operating temperature is not attained. The ensuing interval is, however, sufficiently long for cooling down to the long term no-load operating temperature.

2.22 Cord Set — An assembly consisting of a flexible cable or cord complete with a non-rewirable mains plus and a non-rewirable mains connector.

2.23 Danger — Electric shock, thermal or electrical burns, mechanical or chemical injury, combustion or explosion or generation of toxic gas, injuring or affecting the patient, intermediary or operator.



1 Special plug for connection to the medical isolated extra-low voltage source
2 Basic safety insulation
3 Enclosure (accessible metal parts)
4 Functional earth terminal
5 Supply input part
6 Output part
7 Motor with accessible shaft

FIG. 5 AN EXAMPLE OF A PROTECTION CLASS III DESIGN

2.24 Detachable Cord — A flexible supply cord connected to the equipment with an appliance coupler (*see* Fig. 2).

Note — The appliance coupler may be rewirable or its mains connector may be part of a cord set.

2.25 Direct Cardiac Application — Use of equipment applied to a patient having a catheter inside the heart or electrodes on the exposed heart.

2.26 Disinfectable Equipment — Equipment of which the satisfactory operation and safety is not impaired when the equipment is disinfected by means allowed in the instructions for use or indicated on the equipment.

2.27 Double Insulation — Insulation comprising both basic safety insulation and supplementary insulation.

2.28 Drip-Proof Equipment — Equipment provided with an enclosure preventing entry of such amount of falling liquid which might interfere with the satisfactory and safe operation of the equipment.

2.29 Duty-Cycle — Ratio of the operating time to the sum of the operating time and the ensuing interval.

Note — In the case of operating times and intervals of varying duration it is calculated as a mean value over a sufficiently long time.

2.30 Earth Leakage Current — Current flowing from the mains part through or across the insulation and through the protective earth conductor.

2.31 Electric Shock — Sensitivity of the human or animal body for electric currents.

2.32 Electrode — A conducting element used for conveying current to and from a medium.

2.33 Electrical Safety Device — Any device such as an interlock which removes the voltage from live parts which become accessible when the enclosure is opened (for example, safety switches, earthing switches and isolating switches).

2.34 Enclosed Medical Gas System — Under consideration.

2.35 Enclosure Leakage Current — Current flowing from the enclosure or part of the enclosure, through an external conductive part other than protective earth, to earth or to another part of that enclosure.

2.36 External Terminal Device — Terminal device by which the electrical connection to other equipment is made.

2.37 F-Type Isolated (Floating) Applied Part — Applied part isolated from all other parts of the equipment to such a degree that the allowable patient leakage fault current is not exceeded when 1·1 times the highest specified mains voltage is applied between the applied part and earth.

2.38 Fixed Equipment — Equipment which is fastened or otherwise secured at a specific location in a building or a vehicle.

2.39 Fixed Mains Socket-Outlet — Mains socket-outlet (intended to be) installed in a fixed wiring system (*see* Fig. 2).

2.40 Functional Earth Conductor — Conductor (intended to be) connected to a functional earth terminal (*see* Fig. 1).

2.41 Functional Earth Terminal — Terminal directly connected to a point of a measuring supply or control circuit or to a screening part which is intended to be earthed for functional purposes.

NOTE — For measuring equipment, this terminal is often termed a 'measuring earth terminal' (*see* Fig. 1).

2.42 Functional Patient Current — Current originating from the equipment and applied to the patient which is necessary for the intended purpose of the equipment.

2.43 Grave Danger — Grave danger exists when there is a high probability that the failure of a protective feature will result in serious injury or death.

2.44 Hand-Held Equipment — Equipment intended to be supported by the hand during normal use and having an equivalent weight/lift effort not exceeding 7 kgf.

2.45 High Voltage — Any voltage over 650 V ac (dc value under consideration).

2.46 Input Part — Part of equipment, not being an applied part, intended to receive an input voltage or current, for example, signals for display, recording or data processing (*see* Fig. 1).

2.47 Inherently Short-Circuit Proof Transformer — Short-circuit proof transformer without any device for automatically opening the input circuit or the output circuit when the transformer is overloaded or when its terminals are short-circuited.

2.48 Interconnection Terminal Device — Terminal device by which internal connections within the equipment or between equipment parts are made.

2.49 Intermittent Operation — Operation in a series of specified identical cycles, each cycle being composed of a period of operation under normal load, without the specified limits of temperature rise being exceeded followed by a rest period with the equipment running idle or switched off.

2.50 Isolated Extra-Low Voltages — Voltage not exceeding 32 V ac (dc value under consideration) at any point of a circuit which is separated from circuits with higher voltages by insulation at least equivalent to that for Class II equipment.

2.51 Leakage Current — Non-functional current through an insulation.

2.52 Live — The presence of a voltage and/or current and/or energy level on a part, which can deliver, when this part is contacted accidentally in normal condition or single fault condition, a current exceeding the allowable leakage current through a prescribed impedance representative for the human body, which is connected between the relevant part and earth or between the relevant part and another accessible conductive part.

NOTE — Extension of this definition concerning non-continuous phenomena, possibly to be expressed as a limit for delivered charge and/or energy, is under consideration.

2.53 Live Parts — Conductors and conductive parts which are live in normal use.

NOTE 1 — Live parts also include the neutral conductor and all conductive parts connected to it, exclude the protective earth conductor and all conductive parts connected to it. Live parts may be parts operating at a potential difference to earth and parts having a potential difference between them.

NOTE 2 — Live parts may be part of the mains part or of an internal circuit or of the applied part (patient circuit).

2.54 Long Term On-Load Operating Temperature — Temperature at which an equilibrium is established between the supplied energy and the dissipated heat (steady state in the case of continuous operation).

2.55 Mains Operated — Condition of equipment indicating that it is operated when connected to a supply mains or is intended for such a connection.

2.56 Mains Part — Entirety of all parts of the equipment intended to have a conductive connection with the supply mains. For the purpose of this definition the protective earth conductor is not regarded as a part of the mains part (*see* Fig. 1).

2.57 Mains Plug — Part integral with or intended to be attached to a flexible cable or cord of equipment, of a cord set and intended to be inserted into a fixed mains socket outlet (*see* Fig. 2).

2.58 Mains Voltage — Voltage difference between two different line conductors of a poly-phase system of a supply mains or the potential difference between the line conductor and the neutral conductor of a single-phase system of a supply mains.

2.59 Mains Terminal Device — Terminal device by which the electrical connection to the supply mains is made (*see* Fig. 1).

2.60 Mechanical Safety Device — Any device which is destined for protection against mechanical hazards by a direct mechanical action.

2.61 Medical Electrical Equipment — All professional electrical and electronic equipment used in medical practice.

2.62 Medical Isolated Extra-Low Voltage — For the purpose of this standard an ac voltage up to and including 24 V and any dc voltage up to and including 50 V, supplied by a medical isolating transformer or by an isolated external battery or by any other external source with equivalent protective qualities.

2.63 Medical Isolating Transformer — A supply transformer being part of a medical isolating transformer assembly.

2.64 Medical Isolating Transformer Assembly — Electrical equipment used in medical practice intended to supply isolated power to medical electrical equipment in order to minimize the likelihood of discontinuity of supply in case of a failure to earth in the isolated power source or in one of the other equipment connected to it.

2.65 Mobile Equipment — Transportable equipment intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means of support.

2.66 Model or Type Reference (Type Number) - Combination of figures, of letters or of both used to identify a certain model of a particular piece of equipment and to establish its relationship to commercial and technical publications, to accompanying documents and between eventually separated parts of the equipment at the moment of delivery.

Note — Although a model or type reference usually denotes a certain performance specification, it may possibly not denote the exact construction, including the applied components and materials. If this is required the model or type reference may be supplemented by a serial number. The serial number may also be used for other purposes.

2.67 Multiple Mains Socket Outlet — Accessory incorporating more than one mains socket outlet.

2.68 Non-inherently Short-Circuit Proof Transformer — Short-circuit proof transformer which incorporates a protective device, such as a fuse, an overload release or a thermal cut-out which is intended to protect the transformer against overheating in case of overloading or short-circuiting.

2.69 Non-rewirable Mains Plug — Accessory so constructed that the flexible cable or cord cannot be separated from the accessory without making it permanently useless.

2.70 Non-rewirable, Non-detachable Cord — Flexible supply cord normally expected to last the life of the equipment.

2.71 Non-Self-Resetting Thermal Cut-Out — Thermal cut-out which requires resetting by the use of a tool or replacement of the part, in order to restore the current.

2.72 Non-Short-Circuit Proof Transformer — Transformer intended to be protected against excessive temperature rise in case of overloading or short-circuiting by means of a protective device which is not incorporated in the transformer.

2.73 **Normal Condition** — Condition in which all means for protection against hazards are operative.

2.74 **Normal Use** — Operation, including stand-by, according to the instructions for use of the normal use corresponding with construction, design and performance.

2.75 **Operational Insulation** — Insulation between live parts which have a potential difference between them and which is necessary for the normal functioning of the equipment.

2.76 **Output Part** — Part of equipment, not being an applied part, intended to deliver an output voltage or current, for example, signals for display, recording or data processing (*see* Fig. 1).

2.77 **Patient** — Any living being (person or animal) subjected to investigation or treatment using medical electrical equipment.

2.78 **Patient Auxiliary Current** — Functional patient current but not including any current intended for the administration of energy to the patient for diagonstic, therapeutic or surgical purposes.

NOTE — A patient auxiliary current may be necessary to detect potentials or currents generated by the patient or to measure impedances of parts of the patient.

2.79 **Patient Centre Equipotential Point** — Point to which equipment connected with and/or used around a patient can be connected for potential equalization purposes.

2.80 **Patient Circuit** — Electrical circuit of which the patient forms a part and which is intended to carry current to a patient (by, for example, conductive path or a capacitive or inductive coupling) or which is intended to detect currents or potentials generated by the patient or to measure impedances of parts of the patient.

2.81 **Patient Environment** — Any area used for the examination or treatment of patients in which intentional or unintentional contact between patient and equipment may occur.

2.82 **Patient Leakage Current** — Current flowing from the applied part via the patient to earth (excluding any functional patient current) or flowing from the patient via an isolated (floating) applied part to earth originating from the unintended appearance of a voltage from an external source on the patient.

2.83 **Percent Average Error** — The percent ratio of the difference between a preset or pre-indicated value and the mean value of a population of observations to the preset or indicated value. The following formula may be used:

Percent average error of the population (PAE) $= \frac{X_P - \bar{X}}{X_P} \cdot 100(\%)$

where

X_p = preset or pre-indicated value, and
$\bar{X}$ = mean value of observations in sample.

2.84 Permanent Connection — Connection that can be loosened only with the aid of tools.

2.85 Permanently Installed Equipment — Equipment that is electrically connected by means of permanent connections using fixed leads protected against mechanical damage.

2.86 Pillar (Tubular) Terminal — Terminal in which the conductor is inserted into a hole or cavity, where it is clamped under the shank of a screw or screws. The clamping pressure shall be applied through an intermediate clamping member to which pressure is applied by the shank of the screw.

2.87 Portable Equipment — Transportable equipment intended to be moved from one location to another while used or between periods of use while being carried by one or two persons.

2.88 Potential Equalization Conductor — Conductive connection between extraneous conductive parts and a potential equalization bus bar.

2.89 Properly Installed — Condition in which at least the relevant instructions concerning installation given by the manufacturer in the accompanying documents are observed and which does not conflict with the requirements specified in IS : 732-1963*.

2.90 Protective Earth Conductor — Conductor to be connected between the protective earth terminal and an external protective system (*see* Fig. 1).

2.91 Protective Earth Terminal — Terminal connected to accessible metal parts of class I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a protective earth conductor (*see* Fig. 1).

2.92 Protective Impedance — Component or assembly of components, the impedance, construction and reliability of which are such that it may be connected between live parts and accessible conductive parts without giving rise to electric shock.

NOTE — For medical electrical equipment 'electric shock' means exceeding of the allowable leakage current in single fault conditions applying to other parts.

2.93 Reinforced Insulation — Improved basic safety insulation with such mechanical and electrical qualities that it provides the same degree of protection against electric shock as double insulation.

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*Code of practice for electrical wiring.

2.94 Restricted Movable Equipment -- Equipment movable within a course or area restricted by means such as rails, guides, pivots, etc.

2.95 Rewirable Mains Plug — Accessory so constructed that a flexible cable or cord to be connected to it can be replaced.

2.96 Rewirable Non-detachable Cord — Flexible supply cord where the method of attachment to the equipment is designed to permit easy replacement.

2.97 Safety Switch — Any switch incorporated in the equipment for safety purposes.

2.98 Screened Cable — A cable in which the insulation of each conductor is separately enclosed in a conducting layer in order to ensure a radial electric field surrounding conductor.

2.99 Screw (Strap) Terminal — Terminal in which the conductor is clamped under the head of the screw.

NOTE — The clamping pressure may be applied directly by the head of the screw or through an intermediate part, such as washer, clamping plate or anti-spread device.

2.100 Self-Resetting Thermal Cut-Out — Thermal cut-out which automatically restores the current after the relevant part of the equipment has cooled down sufficiently.

2.101 Serial Number — Combination of figures or letters or of both which is unique to a particular item of equipment denoting the exact construction of that particular sample of the equipment, and if required, also denoting the location and date of manufacture possibly in a code or key and possibly the relation of a particular sample of the equipment to documents used during or after manufacturing, testing, packing and delivery.

2.102 Short-Circuit Proof Transformer — Transformer of which the temperature rise does not exceed specified limits when it is overloaded or short-circuited. It may be inherently or non-inherently short-circuit proof.

2.103 Short-Time Operation — Operation under normal load for a specified period, starting from cold condition without the specified limits of temperature rise being exceeded, the intervals between each period of operation being sufficient to allow the equipment to cool down to room temperature.

2.104 Single Fault Condition — Condition in which a single means for protection against hazards is defective or a single hazardous condition is present.

2.105 Splash-Proof Equipment — Equipment provided with an enclosure preventing entry of such amount of liquid, splashed from any direction, which might interfere with the satisfactory and safe operation of the equipment.

2.106 Stationary Equipment — Either fixed equipment or equipment which is not intended to be moved from one place to another.

2.107 Sterilizable Equipment — Equipment of which the satisfactory operation and safety is not impaired when the equipment is sterilized as prescribed in the instructions for use or as indicated on the equipment.

2.108 Stud Terminal — Terminal in which the conductor is clamped under a nut. The clamping pressure may be applied directly by a suitable shaped nut or through an intermediate part, such as a washer, clamping plate or antispread device.

2.109 Supplementary Insulation (Protective Insulation) — Independent insulation provided in addition to the basic safety insulation in order to ensure protection against electric shock in the event of failure of the basic safety insulation.

2.110 Supply Circuit — Circuit from which the equipment receives the energy necessary for its function, particularly a circuit which is connected to the electrical energy source.

2.111 Supply Equipment — Equipment which supplies electrical power to one or more other pieces of equipment.

2.112 Supply Mains — Any permanently installed power source, which is not used exclusively to supply equipment.

NOTE — This also includes permanently installed battery systems in ambulances and the like.

2.113 Temperature Switch — Temperature sensing device, the operating temperature of which may be either fixed or adjustable and which is intended to operate during the normal operating cycle of equipment by opening or closing a circuit when the temperature of the equipment or of parts of it reach a predetermined value. It does not make the reverse operation during subsequent parts of the normal operating cycle. It may require manual resetting or be reset automatically at the start of a normal operating cycle.

2.114 Terminal Device — Part of equipment by which electrical connection is made to external conductors or other equipment; it may contain several individual contacts.

2.115 Thermal Cut-Out — Device which, during abnormal operation, limits the temperature of equipment or of parts of it, by automatically opening the circuit or by reducing the current, and which is so constructed that its operating temperature setting cannot be altered by the user.

2.116 Thermostat — Device which is sensitive to temperature and serves to keep the temperature of equipment or of parts of it, between limits preset by the user during normal use by automatically opening and closing the circuit or by varying the current.

2.117 Tool — A screwdriver or any other object which may be used to operate a screw or similar fixing means.

2.118 Transportable Equipment — Equipment which is intended to be easily moved from one place to another whether or not connected to the supply and without an appreciable restriction of range.

Note — Examples of transportable equipment are mobile equipment and portable equipment.

2.119 Type B Equipment — Class I, II or III equipment or equipment with an internal power source having an increased degree of protection against electric shock particularly regarding:

a) allowable leakage currents; and
b) reliability of the protective earth connection (if present).

Note — Type B equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application.

2.120 Type BF Equipment — Type B equipment having an additional protection against patient leakage currents flowing from an external source via the patient and the applied part through the equipment.

2.121 Type CF Equipment — Class I or II equipment or equipment with an internal power source, having a high degree of protection against electric shock particularly regarding allowable leakage currents and reliability of the protective earth connection (if present) and having an additional protection against patient leakage currents flowing from an external source via the patient and the applied part through the equipment.

Note 1 — Class III equipment in combination with a prescribed power supply which supplies medical isolated extra-low voltage to this equipment only may be recognized as type CF equipment, subject to relevant tests.

Note 2 — It shall not be possible to connect any further or other equipment to the medical isolated extra-low voltage source.

Note 3 — Type CF equipment is primarily intended for direct cardiac application.

2.122 Type H Equipment — Class I, II or III equipment or equipment with an internal power source having a degree of protection against electric shock comparable to that of household and similar electrical equipment complying with the relevant Indian Standards.

Note — Type H equipment is not intended for application to a patient.

2.123 Variable Consumption Equipment — Equipment in which the power consumption can vary more than 15 percent due to changes in load impedance of the output circuit or in input signal parameters.

2.124 Watertight Equipment — Equipment provided with an enclosure preventing entry of any amount of water when the enclosure is immersed in water under stated conditions.

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Note — The index has been prepared in accordance with IS : 1275-1958[*]. Index numbers are clause numbers.

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